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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/284,147	03/17/99	LANQUETIN M	GEI-067

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1616	6

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary

Application No.	Applicant(s)
09/284,147	Batcho et al.
Examiner	**Group Art Unit**
Sabiha Qazi	1616

☒ Responsive to communication(s) filed on *Feb 10, 1999*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-10 and 16-20* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-10 and 16-20* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *2*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

First Office Action on Merits

Invention: *The instant invention is drawn to a pharmaceutical compositions of combined estroprogestative combination for simultaneous administration of an estrogenic component and a progestative component derived from 19-nor progesterone in combination of one or more pharmaceutically acceptable, inert, non-toxic excipients, intended for administration by oral route.*

Status of the Application

Claims 1-10 and 16-20 are pending.

Claims 1-10 and 16-20 are rejected.

Claim Rejections - 35 U.S.C. § 112 **(1)**

Claim Rejections - 35 U.S.C. § 112 (1)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> *The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same*

and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1, 2, 4 and 7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Basis of Rejection

1. The term "equine conjugated estrogen" in claims 2, 4 and 7 are of unknown breadth and may encompass thousands of compounds. The nature of "equine conjugated estrogen" are not known. No source, preparative methods or the definition has been provided in the specification.

2. In claim 1 terms "estrogenic component" and a "progestative component" are broad. There is no support for the broad range of these compounds. No source is given in the specification.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)):

1) Breadth of claims.

2) Nature of invention.

3) State of prior art.

4) Level of ordinary skill in the art.

5) Level of predictability in the art.

6) Amount of direction and guidance provided by the inventor.

7) Existence of working examples.

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

1) The nature of the invention:

Instant claims are drawn to a pharmaceutical compositions of combined estroprogestative combination for simultaneous administration of an estrogenic component and a progestative component derived from 19-nor progesterone in combination of one or more pharmaceutically acceptable, inert, non-toxic excipients, intended for administration by oral route.

2) The predictability or lack thereof in the art: There is a general lack of predictability in the pharmaceutical art. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970).

The term "equine conjugated estrogen" in claim 2, 4 and 7 are of unknown breadth and may encompass thousands of compounds

therefore, predicting which compound within the broad genus for a particular use is impossible. The method of preparation of these congugates would be unknown as the preparation cannot be predicted if the natures of derivatives are not known.

3) The amount of direction or guidance present: The disclosure does not present methods of preparation, or any definition of the equine conjugated estrogen It is not known what type of derivative are claimed by the applicants. One skilled in the would not know what to select or get the derivatives, since nothing is described in the specification other than 17β estradiol/nomegastrol acetate and nomegastrol acetate/estradiol valerate. These examples are anticipated and/or obvious over the prior art of record.

4) The breadth of the claims: The nature of equine conjugated estrogen and the source of drug is of unknown breadth and are not defined in the specification. The "equine conjugated estrogen" in claims 2, 4 and 7 are of unknown breadth and are not enabled by the specification.

5) The quantity of experimentation needed: Since the equine conjugated estrogen in claim 2, 4 and 7 are of unknown breadth

the claims are generally broad and since there is a lack of a guidance present in the specification, the skilled artisan would have to undertake undue experimentation to practice the claimed invention commensurate with the scope of the claims.

Claim Rejections - 35 U.S.C. § 112 (2)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> *The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*

Claims 3, 5-7 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Following reason apply:

The terms "preferably" in claims 5-7 and 10 and claim 3 "in particular" in claim 3 are unclear.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the

Board of Patent Appeals and Interferences in Ex parte Wu, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of Ex parte Steigewald, 131 USPQ 74 (Bd. App. 1961); Ex parte Hall, 83 USPQ 38 (Bd. App. 1948); and Ex parte Hasche, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 3 recites the broad recitation of "ester of estradiol", and the claim also recites "in particular estradiol valerate" which is the narrower statement of the range/limitation. These term may be deleted to overcome the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 2, 4, 5, 8-10, 16 and 18-20 rejected under 35 U.S.C. 102(b) as being anticipated by Sitruk-Ware (Acession number 96148040, MEDLINE, abstract of Rev. Prat, (1995), 45(19) pages 2401-2406).

Sitruk-Ware discloses the oral hormonal compositions where the combination of estrogen-progestogen are used for simultaneously delivering a progestogen component such as nomegastrol acetate and 2-5 mg per unit dose of estrogen component such as estradiol to a women during ovarian activity in order to inhibit ovulation. Instant claims are drawn to same compositions.

2. Claims 1, 2, 4, 5, 8-10, 16, 17, 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Conard et al. (Fertility and sterility, vol. 64 (4), (1995), pages 957-962). (See the description under the heading "results" and "conclusion" on page 957; "results" on page 959; Tables 1 and 2 , page 959 and table 3 on page 960 and discussion on 960-961).

The instant compositions are anticipated by the prior art as it composition of the combination of oral estrogen estradiol and nomegestrol acetate progestogen are disclosed.
Instant claims are drawn to same compositions.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 1, 2, 4-10 and 16-20 are rejected under 35 U.S.C. 103(a) as obvious over Conard et al. (Fertility and sterility, vol. 64 (4), (1995), pages 957-962). (See the description under the heading "results" and "conclusion" on page 957; "results" on page 959; Tables 1 and 2 , page 959 and table 3 on page 960 and discussion on 960-961).

Conard et al. teaches the composition of sequential combination of oral estrogen estradiol and nomegestrol acetate

progestogen component 1.5 to 3.75 mg per unit dose. The treatments by the said estrogen-progestogen combinations are useful for treating estrogen deficiency which significantly reduce menopausal complaints. These combinations are also useful for preventing cardiovascular diseases.

The instant claims differ from the reference in having different generic scope. The instant invention is broader than the prior art by claiming the simultaneous administration of estrogenic and progestative compounds whereas prior art teaches estradiol and nomegestrol acetate. (Nomegestrol acetate is a 19-nor-progesterone derivative with potent progestational activity and no androgenicity).

One having ordinary skill in the art would be motivated to prepare additional beneficial composition known for the treatment of menopause complaints etc. the combination with a estrogen and a compound with progestational activity because prior art teaches that estradiol in combination with a progestative compound are useful for harmone replacement therapy, menopause complaints and for preventing cardiovascular diseases.

There has been ample motivation provided by the prior art to prepare such combination when searching for the compositions of the similar activity.

Claim 3 is drawn to estradiol valerate are known esters and property associated with the estradiol would be expected to estradiol unless any unexpected results are seen.

Claims 6 and 7 are drawn to the doses of the estrogen compound. The determination to employ the optimum ranges of the estrogen compound would have been within the skills of the one familiar with the art.

The data in the specification has been considered by the examiner. The results as shown were expected. Nothing unexpected is seen in the data provided in the specification.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha N.

Qazi, whose telephone number is (703) 305-3910. The examiner can normally be reached on Monday through Friday from 8 a.m. to 6 p.m. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Sabiha N. Qazi Ph.D.

9/10/99 **Examiner, 1616**